



UNITED STATES PATENT AND TRADEMARK OFFICE

NOV - 8 2006

Commissioner for Patents  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450  
www.uspto.gov

THERAVANCE, INC.  
901 GATEWAY BOULEVARD  
SOUTH SAN FRANCISCO, CA 94080

In re Application of :  
Mathai Mammen et al :  
Serial No.: 10/696,464 : PETITION DECISION  
Filed: October 29, 2003 :  
Attorney Docket No.: P-142-US1 :

This is in response to the petition under 37 CFR 1.144, filed August 10, 2006, requesting withdrawal of an improper restriction requirement.

BACKGROUND

A review of the file history shows that this application was filed under 35 U.S.C. 111 on October 29, 2003, and contained claims 1-46. In a first Office action, mailed March 20, 2006, the examiner required restriction between the inventions claimed, as follows:

- Group I – Claims 1-33, 39 and 44-46, drawn to compounds of formula I where  $p=1$  and one of W, X, Y and Z is nitrogen or  $N \rightarrow O$  and compositions thereof;
- Group II – Claims 1-17, 20-24, 39 and 44-46, drawn to compounds of formula I where  $p=1$  and two of W, X, Y and Z is nitrogen or  $N \rightarrow O$  and compositions thereof;
- Group III – Claims 1-19, 39 and 44-46, drawn to compounds of formula I where  $p=2$  and one of W, X, Y and Z is nitrogen or  $N \rightarrow O$  and compositions thereof;
- Group IV – Claims 1-17, 39 and 44-46, drawn to compounds of formula I where  $p=2$  and two of W, X, Y and Z is nitrogen or  $N \rightarrow O$  and compositions thereof;
- Group V – Claim 34, drawn to a compound of formula IV;
- Group VI – Claim 35, drawn to a compound of formula V;
- Group VII – Claim 36, drawn to compounds of formula VI;
- Group VIII – Claim 37, drawn to compounds of formula VII;
- Group IX, - Claim 38, drawn to compounds of formula VIII;
- Group X, Claims 40-43, drawn to a method of treating a mammal with a muscarinic receptor antagonist.

An election of species was also required for whichever group was elected.

The examiner reasoned that the compounds of Groups I-IV differed in ring size and bonding arrangements and were patentably distinct. Groups V-IX were indicated as intermediates useful

in forming the compounds of Groups I-IV but could be useful in making other compounds. Group X was argued as a method of use as opposed to the compounds and thus distinct therefrom.

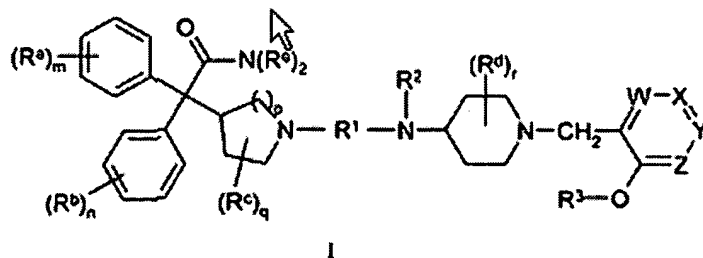
Applicants replied on March 28, 2006, adding claims 44-46 and electing the compounds of Group I with partial traverse with respect to Group II-IV only. Applicants argued that all of the compounds of Groups I-IV are encompassed by the generic formula of Claim I and that they should not be divided, relying on M.P.E.P. 803.02 and *In re Weber*. An election of a single species was also made.

The examiner mailed a new Office action to applicants on May 31, 2006, acknowledging the election of Group I and the species, and the partial traversal of the requirement with respect to Groups I-IV. The examiner maintained the requirement based on different classifications and search burden. The examiner, however, indicated potential rejoinder of Group X, to method claims, if the compound claims were determined to be allowable. The requirement was made Final. The examiner rejected claims 34-38 and 40 under 35 U.S.C. 112, second paragraph, as indefinite, and Claims 40-41 and 43 under first paragraph, as lacking enablement. Claims 44-46 were rejected for obvious double patenting over SN 10/888,855. Claims 1-6, 13-33, 39-41 and 43 were also rejected for obvious double patenting over SN 10/975,657 in view of SN 10/888,855; and claims 7-12, 30, 39-41 and 43 were rejected over the same references for different reasons.

This petition was filed on May 23, 2006, traversing the restriction requirement as being in error. Applicants also filed a reply in which claims 34-38, 40-43 and 46 were canceled and claim 39 was amended. And the rejection of record responded to. The examiner has not taken the case up for action at the present time.

## DISCUSSION

Applicants' petition is directed only to the restriction between Groups I-IV as claims to Groups V-IX have been canceled and Group X is subject to rejoinder. All Groups are directed to the compounds of formula I as shown:



As set forth, the examiner based the restriction requirement of the four Groups on two variables, "p" and W, X, Y and Z, as a group. As can be seen from the structure above "p" determines the ring size of the nitrogen containing ring at five or six members, each of which would be separately classified. W, X, Y and Z also form a heterocyclic ring containing one or two nitrogens. Applicants argue that the above structure forms a proper Markush group and should

not be divided into bits and pieces for examination purposes. Applicants argue that all of the compounds have a common utility and share a substantial structural feature in common and are thus not separable. Applicants state that the 4-amino-1-(pyridylmethyl)piperidine compounds are all useful as muscarinic receptor antagonists. The utility is documented in the specification and elsewhere.

Applicants also argue that the compounds possess a common structure which differs only in that some compounds have an extra methylene unit in the ring structure. However, this is an important difference when searching the compounds. While applicants appear to indicate that these compounds are substituted piperidine compounds, based on the piperidine ring having the  $R^d$  variable, they could just as easily be considered to be 2,2,2-substituted ethylamide compounds wherein two phenyl and one pyridyl or piperidyl rings are the substituents at the 2 position, each being further substituted. In fact, the common or invariant structure is the substituted ethylamide, not the central piperidine ring. However there are two different ethyleamide structures, depending on the value of "p". The examiner has properly divided the compounds of the Markush based on this variable.


The examiner's invocation of the W, X, Y and Z group as a second variable is, however, improper as it is not a part of the common or core structure. Based on the above Groups I-IV are combined to form two Groups based on the value of "p". As applicants have elected Group I, where "p" has a value of 1, Groups I and II are combined as a single Group and Groups III and IV are combined as a single Group and Groups I and II (now Group I) will continue to be examined. Groups III and IV (now Group II) continue to be withdrawn from consideration. Group X will be considered for rejoinder should the claims of Group I be determined to be allowable.

#### DECISION

The petition is **GRANTED-IN-PART.**

**The application will be forwarded to the examiner for consideration of applicants' reply filed August 10, 2006, and further action not inconsistent with this decision.**

Should there be any questions about this decision please contact William R. Dixon, Jr., by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0519 or by facsimile sent to the general Office facsimile number, 571-273-8300.

  
George C. Elliott.  
Director, Technology Center 1600